Physiological deterioration in the Emergency Department

Physiological deterioration in the Emergency Department: The SNAP40-ED study

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Abstract

Continuous novel ambulatory monitoring may detect deterioration in Emergency Department (ED) patients more rapidly, prompting treatment and preventing adverse events. Single-centre, open-label, prospective, observational cohort study recruiting high/medium acuity (Manchester triage category 2 and 3) participants, aged over 16 years, presenting to ED. Participants were fitted with a novel wearable monitoring device alongside standard clinical care (wired monitoring and/or manual clinical staff vital sign recording) and observed for up to 4 hours in the ED. Primary outcome was time to detection of deterioration. Two-hundred and fifty (250) patients were enrolled. In 82 patients (32.8%) with standard monitoring (wired monitoring and/or manual clinical staff vital sign recording), deterioration in at least one vital sign was noted during their four-hour ED stay. Overall, the novel device detected deterioration a median of 34 minutes earlier than wired monitoring (Q1, Q3 67,194; n=73, mean difference 39.48, p<0.0001). The novel device detected deterioration a median of 24 minutes (Q1, Q3 2,43; n=42) earlier than wired monitoring and 65 minutes (Q1, Q3 28,114; n=31) earlier than manual vital signs. Deterioration in physiology was common in ED patients. ED staff spent a significant amount of time performing observations and responding to alarms, with many not escalated. The novel device detected deterioration significantly earlier than standard care.

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Introduction

Over the last 15 years there has been increasing focus on the earlier detection of physiological deterioration in the clinical condition of hospital patients with the aim of instigating treatment earlier, reversing the deterioration and preventing adverse outcomes. Less is known about the nature of physiological deterioration in the Emergency Department (ED).

Deterioration may be apparent in some patients as much as 12 hours prior to an adverse outcome.[1] There is increasing focus on detecting this deterioration earlier with the aim of instigating treatment more promptly to prevent adverse events.[2] It is also known that the ED, a complex and dynamic environment, holds potential risk to patients from large volumes of undifferentiated patients, overwhelming demand, patient flow or exit block and critical staffing issues.[3,4] To date, evidence that continuous physiological monitoring improves outcome is limited.[5,6]

The SNAP40-ED study aimed to compare the ability of a prototype ambulatory monitoring device, formerly SNAP-40, now renamed Current Health (Current Health Ltd., Edinburgh, UK) to detect deteriorations in vital sign physiology of ED patients earlier than current standard monitoring and observation charting techniques. Secondary aims included measuring the time ED staff spent performing and charting observations and responding to standard monitoring alarms, assessing how often a change in the vital sign physiology of an ED patient led to a clinical escalation or de-escalation of care, and studying ED patient and staff experience of novel ambulatory versus current monitoring techniques.

Materials and Methods

Design

Single centre, open label, prospective, observational cohort study recruiting high/medium acuity (Manchester triage category 2 and 3) participants, aged 16 years or over, presenting to the ED.

Setting

ED of the Royal Infirmary of Edinburgh (RIE). The RIE sees approximately 120,000 patients per year of whom approximately half are deemed to be majors level (Manchester triage category 2 and 3) acuity.

Endpoints

Primary outcome was time to detection of deterioration (defined as any increase in NEWS score (Table 1).[7,8] Secondary outcomes included clinical staff time spent performing observations and responding to standard monitoring alarms, clinical escalation of care when deterioration is detected and participants and staff rating of experience of both novel and standard monitoring.

Ethics

The study was registered with ClinicalTrials.gov (NCT03179267) and a favourable ethical opinion was obtained from Scotland A Research Ethics Committee (REC reference: 17/SS/0028).

Sample size calculation

A small pilot study in the RIE ED demonstrated that 20% of patients experienced deterioration in NEWS score during their ED stay. Recruiting 250 patients would give 90% power to detect an effect size of 0.468 and 80% power to detect an effect size of 0.404 (paired t-test, two sided p=0.05). We aimed to recruit at least 50 participants triaged to a non-monitored area, and at least 50 participants triaged to continuous monitoring. Other recruited participants had variable levels of observation charting as determined by the treating clinical team. After surveying a group of ED and critical care physicians, we selected an increase in NEWS score of +1 as being a clinically significant endpoint.

Intervention

Participants were approached and enrolled in the ED and after consent (or relative consent if lacking cognitive capacity) had the novel wearable monitoring device placed onto their arm. The information from the novel wearable monitoring device was observed by the research team only, and was not used as an alternative to standard clinical care or clinical observations of the participant whilst they were in the ED. The participant continued to have their vital signs monitored by the clinical team as per standard clinical practice (*i.e.* novel wearable monitoring and standard clinical care monitoring occurred synchronously/in parallel, monitoring the same physiological parameters). Participants were observed throughout their time in the ED. Any novel wearable monitoring device alarm, standard monitoring alarm or standard practice vital sign observation indicating a deterioration in a patient's vital sign physiology (defined as an increase in NEWS score) was recorded.

The novel wearable monitoring device alerted the research team in real time via a tablet application should the participant's vital sign physiology change from one NEWS category to a higher one. The time of each alarm, reason for each alarm (*i.e.* parameter for which the alarm was triggered) and new individual component NEWS score was recorded each time the novel wearable monitoring device sent an alarm to the research team. The participant was monitored by the device for a maximum of four hours during their stay in the ED. The device was removed prior to the participant being discharged from the ED or admitted to the hospital.

As well as recording the novel wearable monitoring device alarms, the research team observed and recorded standard practice being utilised by the clinical team when observing and monitoring the participant's vital signs. The novel wearable monitoring device was used alongside usual care equipment and not instead of it. The research team did not intervene to inform clinical staff except for prespecified extreme situations.

Results

Two hundred and fifty (80.6%) of 310 screened patients agreed to participate. One hundred and thirty-three were male (53.2%) and 238 (95.2%) had cognitive capacity. Fifty-one (20.4%) underwent wired monitoring, while the remainder had their vital signs recorded manually.

Reasons for study participation ending were i) discharged from ED (either home or admitted to hospital; n=192, 76.8%), ii) device worn for 4 hours (n=42, n=16.8%), iii) research staff/device issue (n = 6, 2.4%), iv) device removed by patient (n=7, 2.8%) and v) other (n=3, 1.2%). Table 2 details baseline physiology.

In 82 patients (32.8%) receiving standard monitoring (wired monitoring and/or manual clinical staff vital sign recording) there was at least one alert indicating deterioration in at least one vital sign by one NEWS boundary. The remaining 168 patients (67.2%) receiving standard monitoring had no change in NEWS score throughout their ED stay. The vital sign observations triggering the first deterioration (or rise) in NEWS score were as follows; blood pressure (only) 18, pulse rate (only) 15, respiratory rate (only) 2, temperature (only) 1, oxygen saturations (only) 10 and more than one in 36 patients.

In total, there were 150 standard care vital sign alerts in these 82 initial deteriorations with blood pressure alerting in 33 patients, pulse rate in 46, respiratory rate in 18, temperature in 15, oxygen saturations in 28, a need for supplementary oxygen in 9 and AVPU in 1. A total of forty-six patients (56.1%) had only 1 alert, 14

Table 1. NEWS scoring system.

Physiological parameter	3	2	1	0	1	2	3
Respiratory rate	≤8		9-11	12-20		21-24	≥25
Oxygen saturations	≤91	92-93	94-95	≥96			
Any supplemental oxygen		Yes		No			
Temperature	≤35.0		35.1-36.0	36.1-38.0	38.1-39.0	≥39.1	
Systolic BP	≤90	91-100	101-110	111-219			≥220
Heart rate	≤40		41-50	51-90	91-110	111-130	≥131
Level of consciousness				A			V, P or U

patients alerted in 2 simultaneous categories, 14 in 3, 6 in 4 and 2 patients in 5 simultaneous categories.

ED staff spent a median of 225 seconds (Q1, Q3 158,251) performing and recording each episode of chart observations (n=25) and 899 (Q1 , Q3 285, 1397) seconds responding to an alarm episode (n=25). When a deterioration occurred (n=82), the action taken by the ED clinical team was i) escalation to an ED clinician 10 (12.2%), ii) escalation to a senior nurse 4 (4.9%), iii) escalation not required (*e.g.* senior clinical team already in with patient) 8 (9.8%), iv) no escalation performed as deterioration not noticed 23 (28.1%) and v) deterioration noticed but decision made not to escalate 37 (45.1%).

The novel ambulatory monitoring device detected a deterioration in 220 patients. Seventy-six were associated with a concurrent standard care alert. Analysis of patients where there was a first deterioration observed in both novel device monitoring and standard care monitoring showed the novel device detected deterioration a median of 34 minutes earlier than standard care (Q1 , Q3 8,67, n=73, missing=3; mean difference 39.48, p<0.0001, paired t-test 2-tailed). There were 6 occasions where standard care alert

Table 2. Baseline physiology for all study participants (n=250).

Vital sign	Mean (SD)
Systolic BP	138.7 (23.2)
Diastolic BP	80.6 (15.3)
Pulse	87.7 (20.0)
Respiratory rate	17.4 (3.2)
Temperature	36.7 (0.7)
SpO_2	97.6 (2.0)
	n (%), n=250
Requiring supplementary oxygen	10 (4.0)
Conscious level; AVPU (Alert/Voice/Pain/Unconscious)	249/0/1/0
Total NEWS (See Table 1)	
0	96 (38.4%)
1	78 (31.2%)
2	36 (14.4%)
3	15 (6.0%)
4	10 (4.0%)
5	5 (2.0%)
6	4 (1.6%)
7	1 (0.4%)
8	2 (0.8%)
9	3 (1.2%)
Area of ED patient triaged to	
High Dependency; HD (Triage category 2)	47 (18.8%)
Immediate Care waiting room (Triage category 3)	18 (7.2%)
Immediate Care main ED (Triage category 3)	179 (71.6%)
Stepped down from Resus to HD (Triage category 1 to 2)	6 (2.4%)
Frequency of observations prescribed on ED triage sheet	
Hourly	179 (71.6%)
30 minutes minimum	53 (21.2%)
15 minutes minimum	12 (4.8%)
10 minutes minimum	6 (2.4%)

Table 3. Comparison of standard clinical monitoring and novel device monitoring alerts.

			Novel wearable monitoring device alerts								
			No alert only	BP only	HR only	RR only	Temp only	O2 (only)	Move	More than one	Total
Standard clinical monitoring alerts	No alert (n=168; 67.2%)		24	1	32	25	0	80	0	6	168
	Alert (n=82; 32.8%)	BP only	2	0	3	6	0	6	0	1	18
		HR only	1	0	5	1	0	6	0	2	15
		RR only	0	0	1	0	0	1	0	0	2
		Temp only	0	0	0	0	0	1	0	0	1
		O2 only	0	0	1	2	0	6	0	1	10
		AVPU only	0	0	0	0	0	0	0	0	0
		More than one	3	0	8	13	0	8	0	4	36
		TOTAL	6	0	18	22	0	28	0	8	82
TOTAL			30	1	50	47	0	108	0	14	250

BP=Blood Pressure, HR=Heart Rate, RR=Respiratory Rate, Temp=Temperature, O2=Oxygen Saturations%, AVPU=Alert/Voice/Pain/Unresponsive, Move=Movement.

alerted without novel device alert and 144 novel device alerts without a concurrent standard care alert. Table 3 compares the two monitoring methods. Novel device detected deterioration a median of 24 minutes (Q1, Q3 2,43; n=42, missing=1) earlier than wired monitored patients, and a median of 65 minutes (Q1, Q3 28,114; n=31, missing=2) earlier than manual vital sign monitoring.

The novel device rated highly with more than 90% of participants 'agreeing' or 'strongly agreeing' with all experience ratings including comfort, being happy to wear the device for a longer period and feeling confident in the device. 85.2% found the device more comfortable than standard monitoring and 70.1% felt more confident wearing the device compared to standard monitoring.

Discussion

This work describes the nature of physiological deterioration in ED patients and demonstrated an improvement in time to detection of deterioration using a continuous ambulatory monitoring device. Thirty-three percent of patients had a standard care (*i.e.* wired monitoring and/or manual vital sign recording) deterioration in at least one vital sign variable. ED staff spent a median of almost 4 minutes performing each episode of chart observation and a median of almost 15 minutes responding to a vital sign alarm episode. Continuous vital sign monitoring by fully automated wireless, wearable monitoring devices has the potential to allow nursing staff more time for patient interaction, analgesia, communication and completion of traditional nursing and personal care. Equally, missed alerts and mis aggregation of results have been shown to be common when vital signs have been measured manually.[9] Systems that record continuously and aggregate automatically overcome these issues, with the potential to easily display changes in vital sign trends over time.[10]

Our study did have some limitations. The novel device in this case was a prototype, tuned to be sensitive for the purposes of the trial. The protocol did not include a 'gold standard' measure by which to assess veracity of alarming, so it is unknown whether the alerts generated by the novel device were true or false. However, patients typically deteriorate in a stepwise fashion, so the assumption would be that a real deterioration would register in all modes of monitoring eventually. Subsequent work on the device prior to its commercial release in 2019 markedly increased specificity: vital signs were aggregated into short 'windows' of time that reflected the median of a number of observations. Alerts were also configured around vital signs in combination (for example, a simultaneous change in respiratory rate and oxygen saturation) rather than single parameters.

When a deterioration occurred, we defined the actions taken by the ED clinical team such as instigation of a patient review by an ED clinician or senior nurse as an escalation in care. Future studies should also look at actual changes in patient care or patient management such as described by Fleischman *et al.*[11]

Our definition of deterioration of physiology being an increase in NEWS score was based on a survey of a group of ED and critical care physicians. This was an extremely sensitive outcome measure and may have overrepresented the number of patients with true clinically relevant physiological deterioration. For example, a respiratory rate that changes from 12-20 to 9-11 could have occurred due to normal physiological variation. Similarly, patients with normal, physiological bradycardia whose baseline pulse lies between 40 and 70 may have produced repeating alarms due to physiological decreases in heart rate to below 50. This may explain why many of the ED alarms in this study did not result in changes in clinical management and is the reason for the well reported problem of alarm fatigue.

Monitoring thresholds need to balance not just sensitivity and specificity, but also the capacity to respond to alerts. Almost three-quarters of vital sign alarm episodes were not escalated. Either the deterioration was noticed but a decision was made not to escalate further, or in a third of cases, because the deterioration was not picked up by staff. As our ED was unlikely to have been very different to other EDs, this demonstrated that future research and quality improvement studies need to assess not just the accuracy and reliability of novel monitoring devices,[12] but also their capacity to alert clinical staff to possible physiological deterioration in a way that leads to meaningful clinical behaviours and interactions. A monitor exists as part of a clinical system, it does not stand alone. Key metrics by which devices should be judged include improvement in patient outcome, reduction in clinical and nursing workload, along with cost effectiveness. Finally, this study also showed that patients are extremely comfortable and confident in continuous novel ambulatory monitoring and very open to its integration into emergency care.

Conclusions

Deterioration in physiology was common even in non-resuscitation ED patients (Manchester triage category 2 and 3) and is equally frequent in a single vital sign as in simultaneous categories. Blood pressure, pulse rate and respiratory rate are the vitals that deteriorate most frequently. A novel wearable continuous monitoring device detected deterioration a median of one hour earlier than manual vital signs. ED staff spend a significant amount of time performing observations and responding to alarm episodes, despite many not being escalated.

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